K130936
Page 1 of 3

510(k) Summary

as required by 807.92

1. Company Identification

Konica Minolta, Inc.
No.1 Sakura-machi, Hino-shi, Tokyo 191-8511, Japan
Establishment Registration Number: 3004485675

AUG 2 2 2013

2. Submitter's Name and Address

Shigeyuki Kojima
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Regulations and Standards Section, Quality Assurance Center
No. 1 Sakura-machi, Hino-shi, Tokyo 191-8511, Japan
Telephone: 81-42-589-8429
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3. Date of Submission

March 25, 2013

4. Device Trade Name

AeroDR SYSTEM with P-31

5. Common Name

Digital Radiography

6. Classification regulation

21 CFR 892.1680 (Solid State X-ray Imaging System with MQB)

7. Classification, Product Code

Class II, 90MQB and 90LLZ

8. Predicate Device

AeroDR SYSTEM, 510(k) number K102349 /Class II, 90MQB and 90LLZ

9. Indications for Use

The AeroDR SYSTEM with P-31 is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in general-purpose diagnostic procedures. The AeroDR SYSTEM with

P-31 is not indicated for use in mammography, fluoroscopy, tomography and angiography applications.

10. Device Description

The AeroDR SYSTEM with P31(K130936) is a digital imaging system to be used with diagnostic x-ray systems. It consists of AeroDR Detector, Console CS-7 (operator console). Images captured with the flat panel digital detector can be communicated to the operator console via wired connection or wireless, depend on user's choice.

The following modifications were added to the AeroDR SYSTEM (K102349/ the predicate device) for the AeroDR SYSTEM with P-31(K130936/ the proposed device). The panel size of 10 x 12 inches (P-31) is added to 14 x 17 inches. The materials of the proposed panel also had been evaluated with the latest ISO 10993-1, and had been assured the safety as same as the predicate device. Two accessories were added: one is AeroDR Interface Unit2 designed to be able to replacement and function of both AeroDR Interface Unit and AeroDR Generator Interface Unit. The other is AeroDR Battery Charger2 designed for the 10X12 inches proposed panel (P-31) which can function as same as the AeroDR Battery Charger of predicate device. Irrespective of those minor modifications, the AeroDR SYSTEM (102349) and AeroDR SYSTEM with P-31(K130936) perform same, and also device design、material used and physical properties of both devices are substantially equivalent.

10. Substantial Equivalence to Predicate Device

Although the AeroDR SYSTEM with P-31 has minor differences from AeroDR SYSTEM as described in 9.Device Description, Indications for Use of proposed device and predicate devices are identical, the materials of the proposed panel had been evaluated with the latest ISO 10993-1, and had been assured the safety as same as the predicate device. The electrical safety **(IEC 60601-1)** and the electromagnetic compatibility testing **(IEC 60601-1-2)** had been assured as the predicate device safety as well.

In technological characteristics, Software and Hardware verification and validation, Risk management based on ISO14971 had been completed without problem, performance testing (Bench testing) including Non clinical and clinical testing referring to the **FDA** Guidance for the Submission of510 (k)'s for Solid State X-ray Imaging Device had been conducted and showed equivalent evaluation outcome, which has supported a fact that no impacts in technological

characteristics such as design, material chemical composition energy sauce and other factors of the proposed device were recognized.

The all evaluation results can assure that there are no safety and effectiveness and performance issue or no differences were found in further than the predicate device has which has been regally marketed the United States.
Therefore, we confirmed that. AeroDR SYSTEM with P-31 has the same substantial equivalency to the predicate device, AeroDR SYSTEM has.

11. Conclusion

Comprehensively, we concluded that the AeroDR SYSTEM with P-31 has no safety and effectiveness and performance issue or difference as the predicate devices has. This 510(k) is substantial equivalence as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Konica Minolta, Inc.
% Mr. Russel Munves
STORCH AMINI & MUNVES, P.C.
2 Grand Central Tower
140 East 45th Street., 25th Floor
NEW YORK NY 10017

August 22, 2013

Re: K130936
Trade/Device Name: AeroDR SYSTEM with P-31
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB, LLZ
Dated: July 11, 2013
Received: July 18, 2013

Dear Mr. Munves:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130936

Device Name: AeroDR SYSTEM with P-31

Indications for Use:

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Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) _____K130936_____